Evolving Regulations in *mHealth*

Denise Myshko

Regulators are still working to understand mobile health applications. As a result, unclear guidance is creating a challenge for pharmaceutical companies.

Mobile devices have already changed the way we live and work. Now smartphones and other mobile devices are poised to transform healthcare. Global trends in healthcare are creating an environment where patients and caregivers are incentivized to manage their own health. Mobile devices also provide physicians with a way to be better connected with their patients.

Industry experts say there is an opportunity for pharma companies to reinforce the relationship between physicians and patients and to help better manage disease.

Mobile technology is a game changer in the pharmaceutical industry, says Geoff McCleary, VP of mobile innovation at Digitas Health.

"There has been a proliferation of smartphone and smart mobile technologies," he says. "We have gone from the phone being a handheld device to it being a central server that sits in one's pocket that connects to any number of solutions. The impact of that for pharma companies is that they now have to account for this new layer of service. It's not just going to be about a pill anymore. It's going to be a pill plus an app plus a support program that help drive value."

Our experts say it will be critical for companies to incorporate mobile resources and support services to patients into their strategic planning. But this is challenging because regulatory oversight is still evolving.

Much of the uncertainty is because medical device regulations came about at a time before many of these technology advancements, says Ed Tomlinson, a senior manager in Ernst & Young's performance improvement group.

"At the time, no one envisioned the explosion of technology that we would see," he says. "If we go back to the early 1980s when most of these device registration requirements were coming into place, PCs had barely come into the marketplace. There were no such things as cell phones. Fast forward 30 years, and the explosion of devices, software, and access to information has created a more complex world than was ever envisioned when those standards where put into place."

He says the challenge is to define what the device is from a physical and a software perspective, as well as how the data will be used. Regulators will then look at the impact of that on the safety of patients.

Regulators are working to address some of these issues. In July 2011, the FDA published a draft guidance that aimed to define those apps that would be regulated as medical devices. FDA officials say they expect to finalize this guidance sometime this year. One category involved an application that was an accessory to a medical device already regulated by the FDA, for example, an app that allows a healthcare professional to make a specific diagnosis. Another category is a mobile communications device that uses sensors or other devices, for example, an application that turns a smartphone into an ECG machine to detect abnormal heart rhythms or to determine if a patient is experiencing a heart attack.

Experts say apps that assist with medical decision-making are likely to fall within the scope of this regulation.

Kyle Sutton, senior digital strategist at MicroMass Communications, says the FDA will place a large focus on the degree of risk a person may incur by misusing an mHealth app or by applying any guidance the application gives that resembles medical advice.

"There is still considerable uncertainty about how lines will be drawn between classification as a wellness — read: unregulated — application and a medical application, which is certain to have considerable regulations," he says. "Several health apps have already received 510(k) (medical device) clearance, even in the absence of official guidances."

Harry Greenspun, M.D., senior advisor, at Deloitte Center for Health Solutions, says more clarity is needed from regulatory agencies about what types of apps will be regulated.

"From a pharma perspective, there has always been the question of how engaged can they can be," he says. "This lack of clarity prevents us from getting things done, especially in adverse event reporting and postmarket surveillance. Another big question involves liability and how privacy and security will be managed. There are a lot of apps that don't qualify for any sort of regulation: fitness, tracking diet or exercise, or reminders for medication. But then there is a gray area where companies are clearly interacting with the health of individuals but it is not something that warrants regulations, such as tracking blood sugar or peak flows. At the tip of the pyramid are apps that are connected to medical devices and electronic medical health records, software that may program, for example, an insulin pump. These apps are clearly warranting regulations to make sure they are safe and effective."

Jeff Elton, managing director in life sciences at Accenture Life Science, says there is complexity in developing regulations for mHealth solutions.

"This technology is still in its early days and a lot of the rules of use and interconnections are still being created," he says. "There are devices that need to be able to interact with each other. There are concerns about which en-

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> **DR. HARRY GREENSPUN**
> Deloitte Center for Health Solutions

tity holds which liabilities with the exchange data. There are support tools where the infrastructure code software is part of the clinical decision."

The mHealth Market

The global mHealth market is expected to reach $10.2 billion by 2018 up from $1.3 billion in 2012 at a CAGR of 41.5% from 2012 to 2018, according to Transparency Market Research. The monitoring services segment is in commanding position having contributed about 63% of the global mHealth market revenue in 2012. The global mHealth market is primarily driven by factors such as the increasing adoption of smartphones and rising incidences of chronic diseases.

"We are seeing trends across a wide range of demographic and behavioral segments that show mobile becoming core to how people live, access, and share information, and make decisions," says Dennis Urbaniak, VP and head, U.S. diabetes patient centered unit, at Sanofi US. "The impact of this as a natural influence on health management supports strong gains as long as consumer choice and demonstrated consumer value remain the standard."

"We are seeing a transformational shift from people who are accessing health information tools and services on traditional platforms, such as PCs and laptops, to consuming that information and accessing tools on mobile platforms," says Todd Zander, VP of mobile and emerging media at WebMD.

"We saw 30% of our traffic in the fourth quarter coming to WebMD from mobile," he says. "At first, we saw sensitive conditions skew higher toward mobile, such as Crohn's disease, STDs, and IBS. The biggest topic area, though, is diet and wellness and fitness. We haven't seen a big uptake in the medical condition based apps, although we think it is going to be huge in the next few years."

Mr. Elton says the explosion in mHealth solutions is also being driven by the mandate to implement electronic health records.

"In the United States, we have a balanced implementation now between what's in acute and what's in ambulatory and physician office environments," he says. "It is progressing fairly rapidly. There is a higher utility of mobile solutions that are coming into play, which is why people can have implantable devices, for example, with a network created around the experience. Another example is diabetes management, which requires full-time monitoring of patients to start to look for ways of linking those data to patients. People are also looking at home-based solutions for populations with multiple diseases to monitor patient compliance."

Currently, however, an overwhelming majority of the apps being produced are for consumers — 70% — which is why we are hearing so much about two of the most popular experiences: tracking health and gamification, says Joe Doyle, interactive director at HCB Health.

"Users find it easy to share accomplishments and seek approval from friends and family," he says. "With this steady growth comes an amazing amount of noise. Users can be lost, wondering which experience is right for them. A quick check on the iTunes store shows 37 different apps just for counting calories."

Mr. Doyle says an underserved mHealth marketplace is for sensitive topics such as sexual health, mental health, and addiction.

"Studies suggest that more people turn to their mobile devices to search for keywords related to these conditions vs. those who search via a laptop, so an opportunity exists for pharma companies that serve these patient populations," he says.

Dr. Greenspun says the growth of mobile in healthcare is mirroring what is happening in other industries.

"Mobile has certainly transformed everything from travel to finance to shopping," he says. "The real advantage is being able to get information to individuals — provider or patient — at the time of most need."

Dr. Greenspun says one of the biggest issues that pharmaceutical companies confront is the move toward value, including the consideration about how providers and pharma will be reimbursed based on the value of the results they achieve.

"A lot of the value driven by pharma depends on patient adherence," he says. "This is where mobile can have a distinct advantage.

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> @ormshr

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Mr. Sutton says consumers and healthcare professionals can expect an increased prevalence of mHealth applications designed to work in tandem with medical hardware.

"The hardware will range from other medical devices, such as glucose meters to pieces of wearable technology designed to report stats around activity indirectly correlated to health outcomes like pedometers," he says. "The current trend among device manufacturers and application developers is to produce proprietary hardware-software combinations, but a few innovators in the space have started to build applications that are hardware agnostic, meaning they can interface with devices from several manufacturers. The end results are hardware that exists almost exclusively to gather data and consumers who are empowered with a number of options to make their data actionable using applications that best suit their needs. If this trend continues — and many would argue that it should — stakeholders can expect to see increased standardization on both sides of the hardware/software equation."

mHealth Strategies

Mr. Sutton says developers should first consider whether their application leans more toward a wellness app or a medical app.

"A wellness app tracks factors related to a user's overall health in a very general sense in the absence of diagnosis or recommendation," he says. "A medical app diagnoses and/or tracks a disease and generates data that may be shared with healthcare providers at the user's choosing. Medical apps may also provide automated, treatment-related feedback. If any of these elements are present in the intended solution, developers should consider 510(k) clearance. The same holds true for applications that aspire to interface with a piece of hardware that has been classified as a medical device."

He says, however, that regulatory considerations should not trump discussions on how the application will be meaningful in the lives of the user base.

"Pharma is shifting toward an increased focus on lasting patient outcomes, not just medication adherence or temporary behavior change," he says. "Mobile health strategies should reflect these considerations."

Pharma has an important strategic choice to make when it comes to mobile health applications: Are apps a marketing adjunct or a healthcare product, questions David Ormesher, CEO of closerlook.

"If the goal is to take a legitimate leadership position in the mashing of technology, healthcare, and user experience, investments in mobile health should be approached the same way a brand team would approach a new product line: it needs a coherent business model and specific financial and clinical outcome endpoints," he says. "This is a new business category, not just a media channel."

He suggests pharma companies may be letting a watershed business opportunity slip away to technology interlopers.

"Other than healthcare professionals, who but pharma has more experience with patients, from clinical trials through individual care?" Mr. Ormesher asks. "The industry's vast tactical insights into patient habits and preferences could be harnessed to build the next generation of efficacious mHealth tools. And pharma companies know how to get stuff approved by the FDA far better than a Silicon Valley tech startup. With its deep knowledge of the regulatory process, the industry should be able to streamline time-to-market and time-to-value much better than mobile health companies."

But other experts say it's important to team up with nontraditional partners, such as network and other technology companies.

"There is a good opportunity there to share knowledge and potentially identify market opportunity that could improve persistence or compliance of patients in taking the drugs or improving outcomes or efficacy of the drugs," Mr. Tomlinson says. "At the same time, the electronics company or nontraditional partner may be helping to sell device or bandwidth, bundled services, or provide additional information to hospitals and healthcare providers. I see a lot of synergies between two companies that might not have collaborated in the past."

Mr. Zander says the opportunity for pharma companies isn't necessarily to build their own apps.

"They can partner with publishers that have large audiences and figure out how to integrate their brand message into integrated apps and mobile Web experiences," he says. "It is no longer mobile user vs. tablet user vs. PC user. It's about one audience. It's about reaching an audience on any screen."

Mr. Doyle says companies should aim to mimic natural mobile behaviors as they relate to health.

"Using context to deliver satisfying experiences in the moment will produce the most popular applications, with word of mouth and reporting helping to drive downloads and usage," he says. "User experience is now more important than ever, and should be a large part of the budget companies set aside." PV

Questions for Pharma Considering mHealth

- Do companies have the competencies that are required to provide care/disease management offerings linked with mHealth services?
- What are companies' abilities to achieve critical mass with patients, especially compared with payers who typically already have this type of influence?
- What are companies' abilities to influence providers to adopt new platforms, especially if they have little influence over their reimbursement?
- What are companies' credibility among consumers and healthcare providers in providing mHealth services?
- If companies don't offer services relevant to the new healthcare model, will they be relegated to providing commodity products?
- Would access to information obtained through mHealth offerings substantially change companies' insights into treatments?

Source: Accenture

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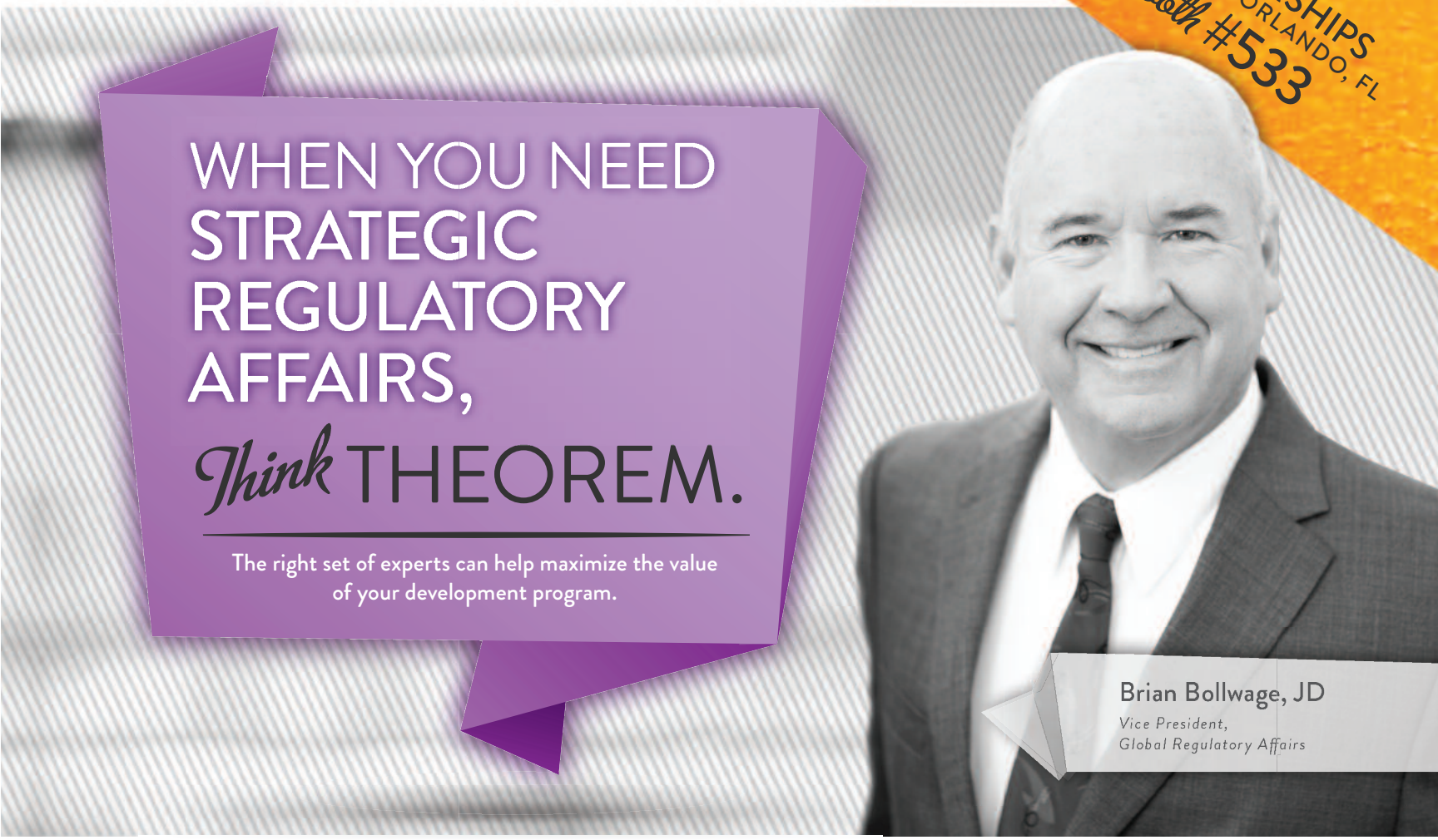

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